

Notice of Allowability

Application No.

09/643,755

Examiner

Cathy K. Worley

Applicant(s)

VAN ROOIJEN ET AL.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on 10/23/07 and interviews on 12/17/07 and 12/20/07.
2. ☒ The allowed claim(s) is/are 1,3,10,13-17 and 21-23.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 563.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Oct. 23, 2007, has been entered.

2. Claims 2, 4, 18-20, and 24-28 have been cancelled in the amendment filed on Oct. 23, 2007; and claims 5-9, 11, and 12 are cancelled by Examiner's Amendment (see below).

3. The rejection of claims 1, 3, 5-17, and 21-23 under 35 U.S.C. 103(a) as being unpatentable over Willmitzer et al in view of Kusnadi et al is withdrawn in light of the Affidavit provided on Oct. 23, 2007, showing that the methods taught by Kusnadi et al would inactivate recombinant chymosin.

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as

provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Micheline Gravelle on Dec. 20, 2007. A summary of the interview is included in the attached interview summary form.

The application has been amended as follows:

IN THE CLAIMS:

Claims 2, 4-9, 11, 12, 18-20, and 24-28 are cancelled without prejudice.

1. (currently amended) A method for the production and isolation of chymosin in a plant seed comprising an oil fraction said method comprising:

a) introducing into a plant cell a chimeric nucleic acid ~~sequence~~ molecule comprising in the 5' to 3' direction of transcription:

1) a seed-specific promoter capable of regulating transcription in said plant cell operatively linked to;

2) a second nucleic acid sequence encoding a chymosin polypeptide and comprising SEQ ID NO:1 operatively linked to;

3) a third nucleic acid sequence capable of terminating transcription in said plant cell;

- b) growing said plant cell into a mature plant capable of setting seed wherein said seed contains chymosin;
- c) obtaining seed from the mature plant wherein the seed contains at least 0.5% (w/w) chymosin; and
- d) isolating said chymosin from said seed using a method comprising:
 - (i) crushing the plant seed in the presence of water or a buffer to obtain crushed plant seed;
 - (ii) fractionating the crushed plant seed into an oil fraction, aqueous fraction and a fraction comprising insoluble material;
 - (iii) contacting the aqueous fraction with a protein binding resin; and
 - (iv) recovering chymosin from the protein binding resin such that said chymosin is purified and biologically active.

17. (currently amended) A method for the production of plant seeds comprising an oil fraction containing at least 0.5% (w/w) chymosin in the total seed protein and the isolation of the chymosin from the seeds comprising:

- (a) introducing into each of at least two plant cells a chimeric nucleic acid ~~sequence~~ molecule comprising in the 5' to 3' direction of transcription:

- 1) a seed-specific promoter capable of regulating transcription in said plant cell operatively linked to;
 - 2) a second nucleic acid sequence encoding a chymosin polypeptide and comprising SEQ ID NO:1 operatively linked to;
 - 3) a third nucleic acid sequence capable of terminating transcription in said plant cell;
- (b) growing each plant cell into a mature plant capable of setting seed;
 - (c) obtaining seed from each mature plant;
 - (d) ~~detecting~~ measuring the levels of chymosin in the seed of each plant obtained in step (c) or in the seed of a plant generated from the seed of a plant obtained in step (c);
 - (e) selecting plants that contain at least 0.5% (w/w) chymosin in the total seed protein; and
 - (f) isolating said chymosin from said seed using a method comprising:
 - (i) crushing the plant seed in the presence of water or a buffer to obtain crushed plant seed;
 - (ii) fractionating the crushed the plant seed into an oil fraction, aqueous fraction and a fraction comprising insoluble material;

(iii) contacting the aqueous fraction with a protein binding resin;

and

(iv) recovering chymosin from the protein binding resin such that
said chymosin is purified and biologically active.

EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

5. The following is an examiner's statement of reasons for allowance:

The nucleic acid sequence of SEQ ID NO:1 is free of the prior art; therefore, the amended claims are neither anticipated nor obvious over the prior art because the amended claims include the nucleic acid sequence of SEQ ID NO:1.

In a telephone interview with Micheline Gravelle, the Examiner indicated that a new rejection under 35 USC 103 would be required if the claims were not limited in scope to methods that utilize nucleic acids comprising SEQ ID NO:1. In the interest of expediting prosecution, the Applicant agreed to Examiner's amendments that limited the claims as suggested by the Examiner.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Claims 1, 3, 10, 13-17, and 21-23 are allowed.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner has a variable schedule but can normally be reached on M-F 10:00 - 4:00 with variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW


PHUONG T. BUI
PRIMARY EXAMINER